SUMMARY OF THE
REGULATORY COORDINATION COMMITTEE MEETING
JANUARY 13, 1999

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, January 13, 1999, at 9 a.m. Eastern Standard Time (EST) as part of the Fourth NELAC Interim Meeting in Bethesda, MD. The meeting was led by its chair, Dr. Carl C. Kircher of the Florida Department of Health, Bureau of Laboratories. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to review the ISO 17025 draft document, to discuss the U.S. Environmental Protection Agency (EPA) regulatory agenda, and to discuss promulgation of the NELAC standards into state regulations and the inclusion of Indian Tribal Nations as voting members in NELAC.*

INTRODUCTION

Following an explanation of the committee's charge and an introduction of the committee members, Dr. Kircher reviewed the agenda and the ground rules for the meeting. He directed participants to prepared hand-outs available to them at the rear of the room. The committee briefly reviewed the minutes for the previous meeting. The minutes were unanimously approved by the committee.

REVIEW OF ISO 17025 DRAFT

Ms. Roxanne Robinson reviewed the draft International Standards Organization (ISO) 17025 document that had been given to participants as a handout. This draft document was made available to the international community for comments. Comments from the United States were funneled through the American National Standards Institute (ANSI) to the working group responsible for the drafting of the standard. The United States, along with Australia and some European countries, cast a negative vote against the standard with two substantial comments. These comments concerned the document's lack of clarity with respect to the need for testing laboratories to establish limits for uncertainty of measurements and its lack of clarity with respect to traceability to the *Systeme International* (SI) unit. If these issues are resolved, the United States will vote affirmatively. When the document is final, the guide will become a standard. It will be more clearly understood at that time that it is a requirements document. International accrediting bodies have agreed to implement the standard and require compliance on the same date. This date has not yet been decided. Ms. Robinson commented that although the document has been dramatically reformatted from ISO 25, it is not dramatically different in content. An exception to this statement is in the area of sampling. Sections 5.7 and 5.10.3.2 of ISO Draft 17025 address sampling in much greater detail than in ISO Guide 25. The document's quality systems sections are in line with ISO 9000.

Following Ms. Robinson's introduction of ISO 17025 Draft, Mr. David MacLean briefly reviewed the document, with particular emphasis on the management and technical requirements constituting Sections 4 and 5. He encouraged participants to pay careful attention to the use of words such as "shall," "must," and "required," which allow no discretion, versus words such as

"may," "should," and "as appropriate," which allow a degree of discretion and judgement. Mr. MacLean also explained that the notes in the preamble are clarification to help understand and interpret the draft standard. They are not part of the standard itself. The sections that address the two specific concerns expressed by the United States are Section 5.4.7.2 and Section 5.6.2.

Considerable discussion of the draft standard ensued. It was noted that members of the Quality Systems Committee have requested a copy of the document and are reviewing it in order to reformat Chapter 5 of the NELAC standards to be consistent with ISO 17025. Participants commented that the ISO 17025 Draft has strong areas and weak areas and singled out performance-based measurement systems (PBMS) as a strong area. A participant noted that Section 4.9 (Control of nonconforming testing and/or calibration work) does not address the issue of "flagging" nonconforming data, and commented that it is not uncommon to encounter nonconforming data. In response the committee directed the participants to Section 4.9.1.c, which mentions "any decision about the acceptability of the nonconforming work," as pertinent to that issue. There was also some discussion of an anticipated delay in finalizing the document. This delay may be attributable, in part, to attempts to harmonize ISO 9000 and ISO 14000.

One committee member expressed the need for a careful committee review of ISO 17025 Draft from the perspective of state and federal regulatory programs, as well as from the laboratory perspective, before making any recommendation concerning the document. Participants questioned whether the committee intended to send the draft document to each of the NELAC committee chairs. In response to these comments and questions, Dr. Kircher proposed that the committee investigate the document's impact on laboratory accreditation and submit their findings in a formal report to the NELAC Board of Directors, the Environmental Laboratory Accreditation Board (ELAB), and all committee chairs. This motion for formal action was unanimously passed by the committee and was designated an action item. The report will be completed by April 1, 1999, and will be posted on the NELAC web page sometime after that date. The committee encouraged participants to comment on the report after it is posted and noted that it will be available for discussion at the annual meeting.

DISCUSSION OF EPA REGULATORY AGENDA

Ms. Jan Jablonski introduced a handout summarizing the October 1998 EPA Regulatory Agenda. The semiannual regulatory agenda is published in April and October. It is a tracking tool that informs Congress and other interested parties of EPA's proposed administrative changes to federal regulations. Ms. Jablonski explained that the information is compiled government-wide and that deadline dates often change. Consequently, some of the items may already be out-of-date by the time the agenda is published. It was suggested that either the summary table or a link to an appropriate web site be posted on the NELAC web page. Dr. Kircher noted that the April 1998 version of the EPA Regulatory Agenda is currently posted on the web page. He suggested updating it with the October 1998 version. A participant suggested including a link to the University of Massachusetts web page from which useful regulatory agenda information is available. The committee agreed to post received comments on the draft handout and to provide the October 1998 regulatory agenda summary table and web page link information to the NELAC internet site by April 1, 1999. The committee also agreed to receive and review the April 1999 regulatory agenda by NELAC V.

NEW BUSINESS

Dr. Kircher introduced two items of new business. First, he encouraged participants to share any experiences, from a regulatory coordination perspective, of attempts to promulgate NELAC standards into state or federal regulations for accrediting authority. Dr. Kircher also shared his own experiences in the state of Florida. The NELAC standards, although useful, contain a great deal of information which might prove confusing to testing laboratories. Dr. Kircher suggested that states consider segregating portions of the standards with which testing laboratories need to comply in order to minimize their confusion. To that end the committee has prepared a cut-and-paste document containing only the portions of the standard applicable to the testing laboratories. The committee offered this "NELAC For Laboratories" for consideration and review. Dr. Kircher identified the following concerns based on his experience:

- The NELAC standards have the potential to be confusing. Dr. Kircher emphasized that the standards need to be standards and not drafts.
- Although the states are responsible for accrediting testing laboratories, the private sector will train on-site assessors. This may present the potential for conflict of interest.
- Although NELAC provides uniform national standards, the states are responsible for training themselves until the proposed assessor training is available. We have yet to see how uniform the assessor qualifications will be until that time.
- Participation in NELAC is voluntary. The states must be careful to decouple voluntary standards from legal issues.

A participant from the state of Oregon shared her experiences. She noted that each state has its own problems and solutions in becoming an accrediting authority and that the state of Oregon has somewhat vague statutes. Oregon has never had a laboratory accreditation program. Therefore, they are using NELAC as a vehicle to move the issue to legislation.

Discussion turned to the spreadsheet handouts listing program analytes. A participant from the Program Policy and Structure Committee asked whether it is the Regulatory Coordination Committee's recommendation that the list of analytes be used to flesh out Figure 1-3 in Chapter 1 of the NELAC standards. The committee responded that the Program Policy and Structure Committee might use the list as a starting point. It was noted that the Program Policy and Structure Committee already has in place an action item concerning this issue. Nancy Wentworth of the EPA, noted that EPA needs a complete list of program analytes for the national database and that any assistance would be greatly appreciated. After considerable discussion, it was decided by acclamation that the Regulatory Coordination Committee will make a formal recommendation to the Board of Directors endorsing the Program Policy and Structure Committee's action item and offering help and support to the committee and the Board of Directors in the form of the spreadsheets delineating analytes. It was also suggested that the list(s) find a home as an appendix to Chapter 1 of the NELAC standards.

The second item of new business consisted of discussing the committee's support for the inclusion of Indian Tribal Nations in NELAC. Existing language in the Constitution and Bylaws invites

their participation in NELAC as sovereign nations with the same status as states. The committee recommended that the Indian Tribal Nations be invited to participate in annual meetings as voting members, and that the Membership and Outreach Committee afford them the credentials necessary to participate as voting members. A participant questioned whether each Tribal Nation on each reservation would have one vote. Dr. Kircher answered in the affirmative but pointed out that very few nations would actually be relevant to the requirements concerning testing laboratories. He anticipated only the Navajo nation in Arizona, two nations in Washington associated with the Hanford nuclear site, and one tribe in Michigan. It was agreed that the committee would formally endorse the inclusion of Indian Tribal Nations in a recommendation to the Program Policy & Structure and Membership and Outreach committees.

CONCLUSION

There being no further business, the meeting was adjourned.

Attachment A

ACTION ITEMS
REGULATORY COORDINATION COMMITTEE MEETING
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Item No.	Action	Date to be Completed
1.	Committee to investigate impact of ISO 17025 on laboratory accreditation and report to Board of Directors, committee chairs, and ELAB	April 1, 1999
2.	Committee to post October 1998 EPA Regulatory Agenda and link to relevant web site on NELAC internet site	April 1, 1999
3.	Committee to receive and review April 1999 EPA Regulatory Agenda	NELAC V
4.	Committee to endorse Program Policy and Structure action item concerning analytes and offer help and support in the form of spreadsheets delineating analytes	Immediate
5.	Committee to recommend to Board of Directors and Membership and Outreach the inclusion of Indian Tribal Nations as voting members of NELAC	Immediate

Attachment B

PARTICIPANTS
REGULATORY COORDINATION COMMITTEE MEETING
JANUARY 13, 1999

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